

REMARKS

Status of the Application and Claim Amendments

Claims 24-35 and 41-42 are currently pending. The Office had withdrawn claims 36-40 and 42 due to an earlier restriction and election of species requirement under PCT Rules 13.1 and 13.2. In this Reply, Applicant cancels non-elected claims 36-40 and amends claims 28 and 31. Applicant also thanks the Examiner for acknowledging the priority claims.

Applicant amends claims 28 and 31 herein to recite in part oligopeptides or polypeptides "comprising a length of at least 7 amino acids, and comprising position 85 of SEQ ID NO:12." As described in more detail below, those amendments are fully supported by the application as a whole and does not introduce new matter. See, for example, pages 10-14 of the specification and SEQ ID NOS:12-30. In particular, see page 12, line 8, to page 13, line 21, of the application text, which explains that oligopeptides or polypeptides of the invention may specifically include those with a length of 7 or larger and that encompass one or more of positions 54, 61, 72, 73, 74, 75, 76, 78, 85, 87, and 94 of SEQ ID NO:12, as described in more detail below.

Hence, Applicant respectfully requests the entry of the amendments to claims 28 and 31.

Rejoinder of Method Claim 42

The Office has apparently refused Applicant's request to rejoin method of use claim 42 to the application once the Office considers the elected composition and method of manufacturing claims 24-35 and 41 to be allowable. (Office Action at pages 2-3.) Applicant respectfully submits that the Office has not sufficiently explained why

claim 42 does not meet the Office's rejoinder policy expressed in M.P.E.P. § 821.04.

Specifically, the Office does not explain why it considers that claim 42 "would require an additional search of the art" even after the Office concludes that the elected oligopeptides and polypeptides used in the method of claim 42 are novel and nonobvious. (Office Action at page 2.)

The Office's policy of rejoining method claims to elected product claims is based in part on binding court precedent. For example, the case of *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995) explains that a process requiring a novel and nonobvious reagent should also be considered novel and nonobvious. Specifically, the Court explained in *Ochiai*, that if a process requires a material that was not known and not obvious from the prior art, the process must also be novel and nonobvious. In such a situation, no additional search of the art is needed.

Applying that reasoning to the claims at issue here, no further search of the art should be necessary once claim 42 is ripe for rejoinder to the elected claims 24-35 and 41. That is because the method of claim 42 cannot be conducted without using at least one of the oligopeptides or polypeptides of claims 24, 26, 28, 29, or 31, from which claim 42 depends. Once the Office considers those elected compositions to be novel and nonobvious, no further search of the art should be necessary.

For that reason, if the Office persists in refusing to rejoin claim 42, Applicant reserves the right to file a petition at the appropriate time.

Claim Objections

The Office objects to claim 29, asserting that claim 29 contains reference to a non-elected invention. (Office Action at page 3.) Applicant requests the withdrawal of this objection.

The Office has issued an election of species requirement according to PCT Rules 13.1 and 13.2 on August 11, 2006, to which Applicant responded by provisionally electing SEQ ID NO:12, with traverse. (See page 2 of the August 11, 2007, restriction/election requirement under the PCT rules.) Thus, once the Office considers the elected species to be free of the prior art, Applicant expects the Office to continue its search to cover the non-elected species to the extent necessary to examine claim 29 and any generic claims, according to the Office's policy of M.P.E.P. § 803 and PCT Rules 13.1 and 13.2.

Claims 28 and 31 Are Novel Under 35 U.S.C. § 102

The Office maintains its rejection of claims 28 and 31 as allegedly anticipated by published PCT application WO01/40279 to Stuyver et al. ("Stuyver"). (Office Action at page 4.) The Office contends that a stretch of 6 amino acids including amino acid 85 includes species that are not novel in view of Example 3 of Stuyver. (*Id.*) Applicant assumes that the Office is referring to the HBsAg sequences of Figure 6 of Stuyver in making this rejection, as Example 3 makes reference to those sequences, and as the only sequence specifically recited in Stuyver's Example 3 is Stuyver's SEQ ID NO:155, which appears to be unrelated to the claimed SEQ ID NO:12 and does not appear to be an HBsAg sequence.

This rejection is now moot due to the amendments to claims 28 and 31. For example, claim 28 now recites an “oligopeptide or polypeptide, comprising at least 5 consecutive amino acids from SEQ ID NO:12, and comprising at least one of the amino acid positions 54, 61, 72, 73, 74, 75, 76, 78, 87, and 94 of SEQ ID NO:12, or comprising at least 7 consecutive amino acids from SEQ ID NO:12, and comprising at least amino acid position 85 of SEQ ID NO:12.”

Applicant also provides a chart below that compares SEQ ID NO:12 to the equivalent portion of Stuyver's HBsAg sequences. Differences are shown in bold text. The only sequence in which position 85 is the same as in SEQ ID NO:12 is Stuyver's Gen D. However, in that sequence, both of positions 80 and 87 differ from SEQ ID NO:12.

Pos. No.	80	81	82	83	84	85	86	87	88	89	90
SEQ ID NO:12	Lys	Thr	Cys	Thr	Thr	Thr	Ala	His	Gly	Thr	Ser
Stuyver Gen A	Lys	Thr	Cys	Thr	Thr	Pro	Ala	Gln	Gly	Asn	Ser
Stuyver Gen B	Lys	Thr	Cys	Thr	Thr	Pro	Ala	Gln	Gly	Thr	Ser
Stuyver Gen C	Lys	Thr	Cys	Thr	Ile	Pro	Ala	Gln	Gly	Thr	Ser
Stuyver Gen D	Arg	Thr	Cys	Thr	Thr	Thr	Ala	Gln	Gly	Thr	Ser
Stuyver Gen E	Arg	Thr	Cys	Met	Thr	Leu	Ala	Gln	Gly	Thr	Ser
Stuyver Gen F	Lys	Thr	Cys	Thr	Ala	Leu	Ala	Gln	Gly	Thr	Ser
Stuyver Gen G	Lys	Thr	Cys	Thr	Thr	Pro	Ala	Gln	Gly	Asn	Ser

Any sequence of at least 7 consecutive amino acids from SEQ ID NO:12 that includes position 85 must include at least one of positions 80 or 87 as well. Thus, Stuyver does not teach or suggest an amino acid sequence “comprising at least 7 consecutive amino acids from SEQ ID NO:12, and comprising at least amino acid

position 85 of SEQ ID NO:12." Applicant accordingly requests the withdrawal of this rejection.

Claims 28 and 31 Have Written Description Support Under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 28 and 31, asserting that the phrase "comprising at least 6 consecutive amino acids from SEQ ID NO:12, and comprising at least amino acid position 85" introduces new matter. (Office Action at pages 4-5.)

While this rejection is moot in light of the amendments to claims 28 and 31, Applicant nonetheless addresses the support for the amended claims reciting, for example, a sequence "comprising at least 7 consecutive amino acids from SEQ ID NO:12, and comprising at least amino acid position 85."

In making this rejection, the Office has overlooked that written description support does not require absolute, word-for-word support in a patent application text. In fact, literal support is not even the standard, as claims may also be supported implicitly or impliedly from the application as a whole. See M.P.E.P. § 2163 *et seq.*

However, in this case, one of ordinary skill in the art would conclude that Applicant was in possession of claims 28 and 31, as presently amended, at the relevant time and that the application text literally supports all of the elements of those claims. For example, page 12, lines 8-14, explains that the invention includes oligopeptides or polypeptides with "an amino acid sequence which is a constituent sequence of SEQ ID NO:12 containing at least 5 consecutive amino acids of SEQ ID NO:12, . . . including one of the positions 54, 61, 72, 73, 74, 75, 76, 78, 85, 87, and 94." The specification immediately goes on to say, at page 12, lines 16 to 19, that this "constituent sequence,"

meaning the constituent sequence of SEQ ID NO:12 just referenced, “preferably comprises at least 6, **more preferably at least 7**, most preferably at least 8, consecutive amino acids of the amino [acid] sequence shown in SEQ ID NO:12.”

(Emphasis added.) Those sentences provide literal support for claims 28 and 31 both as previously presented and as currently amended. No more is needed. Similar discussions are also included at page 12, line 35, to page 13, line 21. Longer sequences are also specifically recited in the text that follows at lines 12-29.

Thus, claims 28 and 31 are fully supported by the application as filed and Applicant requests the withdrawal of this rejection.

Claims 28-35 and 41 Are Enabled Under 35 U.S.C. § 112, First Paragraph

Finally, the Office asserts that the elected claims are not enabled throughout their full scope. Specifically, the Office contends that oligopeptides of 5 or 6 amino acids in length, as recited for example in claims 28 and 31, are not enabled for use. (Office Action at pages 5-7.)

Applicant traverses this rejection because the Office does not present a *prima facie* case of lack of enablement.

The United States courts require Examiners to support every patentability rejection with substantial evidence, such as citations to the technical literature or objective, fact-based reasoning. See, e.g., *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 1999). Without such substantial evidence, the courts or the Board of Patent Appeals and Interferences cannot properly evaluate the veracity of the Office’s contentions.

The Office contends here that it would require undue experimentation to use oligopeptides according to the claims that have 5 or 6 amino acids, for example, as epitopes to make antibodies. The Office makes an unsupported statement that the art teaches that peptides less than 10 amino acids in length are allegedly “nonimmunogenic.” The Office does not provide any evidence to support that argument, such as a citation to the scientific literature or to the present record. Nor does the Office present any objective, fact-based reasoning to support such a statement.

In *Zurko*, the Court explicitly pointed out that the Office cannot establish a *prima facie* case of unpatentability based on such unsupported, conclusory statements about what might or might not be common knowledge in the art. The Court explained that an “assessment of basic knowledge and common sense [that is] not based on any evidence in the record . . . lacks substantial evidence support.” *Zurko*, 258 F.3d at 1385. Thus, because the Office here has not met its burden to establish a *prima facie* case of non-enablement, Applicant is under no obligation to rebut the Office’s contentions.

In addition, as M.P.E.P. § 2164.04 explains, “[a] specification disclosure . . . must be taken as being in compliance with the enablement requirement.” If the Office doubts the disclosure, “it is incumbent upon the Patent Office . . . to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the

trouble and expense of supporting his presumptively accurate disclosure." M.P.E.P.
§ 2164.04, quoting *In re Marzocchi*, 439 F.2d 220 at 224 (C.C.P.A. 1971).

Because this is not a *prima facie* case of enablement for the reasons explained
above, Applicant requests its withdrawal.

Conclusion

Thus, Applicant respectfully requests reconsideration and reexamination of this
application and the immediate allowance of the elected claims and the rejoinder of claim
42. If the Examiner has any questions for Applicant, she is welcome to contact
Applicant's representatives at her convenience.

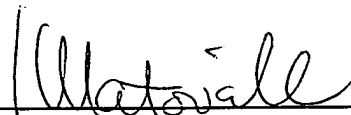
Please grant any extensions of time required to enter this response and charge
any required fees that are not attached to this Amendment to our Deposit Account
06-0916.

Respectfully submitted,

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By: _____



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